AMENDMENTS TO THE CLAIMS

1. (Cancelled)

2. (Previously amended) The method of claim 21, wherein the target protein is a protein that is expressed in malignant cells in an animal.

3. (Previously amended) The method of claim 2, wherein the target protein is Her-2/*neu*, Her-3, Her-4, estrogen receptor, prostate-specific antigen, Epidermal Growth Factor Receptor ("EGFR"), AKT, p13 kinase or Mitogen-Activated Protein Kinase ("MAP kinase").

4. (Previously amended) The method of claim 21, wherein the plurality of control cell pellets are prepared from cultured cell lines.

5. (Previously amended) The method of claim 4, wherein the cultured cell lines express a reproducible amount of the target protein.

6. (Previously amended) The method of claim 21, wherein the quantity of said target protein from each of the control cell pellets is known by determining the quantity of said target protein using an immunological reagent, wherein said immunological reagent is the same or different than the detectably labeled antibody of step (a).

7. (Previously amended) The method of claim 6, wherein the quantity of said target protein from each of the control cell pellets is known by determining the quantity of said target protein by Enzyme Linked Immunosorbent Assay ("ELISA").

8. (Previously amended) The method of claim 21, wherein the quantity of said target protein from each of the control cell pellets is normalized to the total amount of protein in the cell pellet.

9. (Previously amended) The method of claim 8, wherein the quantity of said target protein from each of the control cell pellets is normalized to the total amount of protein per cell.

10. (Previously amended) The method of claim 8, wherein the quantity of said target protein in the calibration curve is expressed as number of target protein molecules per cell.

11. (Previously amended) The method of claim 21, wherein the average optical density of stained target protein per pixel of cellular area is determined using image analysis.

12. (Previously amended) The method of claim 11, wherein said biological sample is stained with a multiplicity of stains, and wherein the image analysis is performed by splitting a signal comprising an optical density of the stained target protein in said biological sample into a multiplicity of signals that are processed using optical filters having different absorption and transmittance properties, so that each signal is specific for one of said multiplicity of stains used to stain the cells in the biological sample.

13. (Previously amended) The method of claim 21, wherein the detectable label is a chromogen or a fluorophore.

14. (Cancelled)

15. (Cancelled)

16. (Previously amended) The method of claim 21, wherein said biological sample is a tissue or cell sample removed from a subject.

17. (Cancelled)

18. (Cancelled)

19. (Previously amended) The method of claim 21, wherein the calibration curve is linear.

20. (Currently amended) The method of claim 21, wherein the ~~immunohistochemically~~ immunohistochemical staining of [(d)] (e) is performed with the same reagents as is used for the ~~immunohistochemically~~ immunohistochemical staining of (a).

21. (Currently amended) A method for determining the quantity of a target protein in cells of a biological sample, the method comprising the steps of:

(a) immunohistochemically staining said target protein in a plurality of control cell pellets using a detectably labeled antibody directed against said target protein, wherein the quantity of the target protein in the plurality of control cell pellets is independently known, and wherein the expression level of the target protein in each of the plurality of control cell pellets is not the same,

(b) identifying the pixels corresponding to the cellular area to be determined for each of the stained plurality of control cell pellets in (a);

(c) determining an average optical density of stained target protein per pixel of cellular area identified in (b) for each of the stained plurality of control cell pellets in (a);

[(c)] (d) generating a calibration curve relating the known quantity of said target protein with said average optical density of stained target protein per pixel of cellular area as determined in [(b)] (c) for each of the plurality of control cell pellets;

[(d)] (e) immunohistochemically staining said target protein from said biological sample using said detectably labeled antibody directed against said target protein;

(f) identifying the pixels corresponding to the cellular area to be determined in said biological sample;

[(e)] (g) determining an average optical density of stained target protein per pixel of cellular area identified in (f) in said biological sample;

[(f)] (h) determining the quantity of said target protein in said biological sample by comparing the average optical density of stained target protein per pixel of cellular

area as determined in step [(e)] (g) in said biological sample to the calibration curve as generated in step [(c)] (d), wherein the quantity of said target protein is derived from the calibration curve.

22. (Previously presented) The method of claim 21, wherein the cellular area is the nucleus.

23. (Previously presented) The method of claim 21, wherein the cellular area is the membrane.